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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,775	10/29/1999	JONATHAN A. BARD	44743-AA-PCT	7729

7590 07/12/2004  
JOHN P WHITE  
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NEW YORK, NY 10036

EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/430,775

Applicant(s)

BARD ET AL.

Examiner

Nirmal S. Basi

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 147, 148 and 153 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 147, 148 and 153 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Amendment filed 4/19/04 has been entered. Claims 1-146 and 149-152 are cancelled. Claims 147-148 and 153 are pending
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action (11/12/03).
3. Drawings filed 4/19/04 are approved by the Examiner.
- 4.

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

Claims 148 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 148 are indefinite because it is not clear when a compounds “specifically bind” to a human Y4 receptor so as to allow the metes and bounds of the claim cannot be determined. It is not clear when compounds “specifically bind” to an Y4 receptor as compared to when they only “bind” to a human Y4 receptor. The specification does not define the term “specifically bind” a human Y4 receptor, and it is not clear what this means, and it is not clear what the difference in scope between “binds” and “specifically binds” is. For example, does “specifically bind” mean bind above background, or bind exclusively to a human Y4 receptor?

Further claim 153 is rejected for depending upon indefinite base claim.

***Claim Rejections - 35 USC § 112, First paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 147-148 and 153 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of obtaining a composition which comprises determining whether a chemical compound binds to a human Y4 receptor expressed on the surface of a mammalian cell transfected with a vector adapted for expressing the receptor in the cell, wherein the human Y4 receptor has an amino acid sequence identical to the amino acid sequence shown SEQ ID NO: 2, does not reasonably provide enablement the use of the human Y4 receptor which is encoded by a nucleic acid sequence identical to the receptor-encoding nucleic acid sequence contained in plasmid PCEXV-Y4 (ATCC Accession No. 75631). The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The deposit of biological material is considered by the Examiner to be necessary for the enablement of the current invention because the claims require availability of the deposit. The deposit of plasmid PCEXV-Y4 (ATCC Accession No. 75631) is not in full compliance with 37 CFR §§ 1.803-1.809 because the specification does not provide a repeatable method for obtaining ATCC deposit and it does not appear to be a readily available material. Although, the aforementioned deposit, if available today from ATCC,

may not be available in the future. An enabled ATCC deposit would satisfy the requirements of 35 USC §112, first paragraph.

To overcome the rejection Applicant must provide evidence that plasmid PCEXV-Y4 (ATCC Accession No. 75631) listed in instant application will be available under the criteria (I)-(V) listed below. Although, the aforementioned cDNA if available today from ATCC, may not be available in the future. An enabled ATCC deposit would satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(I) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(II) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(III) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(IV) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(V) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

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6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi  
Art Unit 1646  
July 8, 2004

  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**